AMENDMENTS TO THE DRAWINGS

Applicants attach and co-file with this document, "REPLACEMENT SHEETS" 1/20, 8/20, 10/20,17/20, 18/20, 19/20 and 20/20 of the Formal Drawings.

REMARKS

I. STATUS OF THE DRAWINGS

Figures 1, 32A, 32B, 33, 34A and 34B were objected to under 37 CFR 1.84(u)(1) for allegedly showing different views that are numbered separately. Figure 31A was objected to under 37 CFR 1.84(q) for allegedly having lead lines pointing to empty space. Applicants address each objection in turn below, as well as discussing additional amendments made within the Figures.

The Applicants now turn to the objection to Figure 1. The Applicants respectfully disagree with the Office Action's statement that Figure 1 allegedly shows different views that need to be numbered separately. The Applicants believe that Figure 1 does not show different views but rather is a flow chart illustrating "the formation of various sub-component parts of an assembled implant according to this invention, from which assembled implants and a kit comprising these parts may be formed." Specification at page 4, lines 22–24. Pursuant to 37 CFR 1.81(b), "[d]rawings may include illustrations which facilitate an understanding of the invention (for example, flow sheets in cases of processes, and diagrammatic views)." Accordingly, the Applicants respectfully submit that Figure 1 is a proper drawing under 37 CFR 1.81(b) and respectfully request that the objection to Figure 1 be withdrawn.

Figure 1 has been amended to add the reference number 105′. Support for this amendment can be found at, for example, page 12, lines 4-11 of the instant Application. No new matter has been added by this amendment. Applicants respectfully request entry of this amendment.

The Applicants now turn to Figure 20G. Figure 20G has been amended to add the reference number 2001. Support for this amendment can be found at, for example, page 16, lines 14-17 of the instant Application. No new matter has been added by this amendment. Applicants respectfully request entry of this amendment.

The Applicants now turn to Figures 22A and 22B. Figures 22A and 22B have been amended to add the reference number 2200. Support for this amendment can be found at, for example, page 16, lines 26-28 of the instant Application. No new matter has been added by this amendment. Applicants respectfully request entry of this amendment.

The Applicants now turn to Figure 30. Figure 30 has been amended to add the reference number 3000. Support for this amendment can be found at, for example, page 22, lines 10-25 of

the instant Application. No new matter has been added by this amendment. Applicants respectfully request entry of this amendment.

The Applicants now turn to Figures 31A and 31B. Figures 31A and 31B have been cancelled. Because Figures 31A and 31B were the only figures on page 18 of the drawings, this page has been removed. The remaining figures have been renumbered and submitted as Replacement Sheets to reflect this cancellation. Applicants respectfully request entry of this amendment. Because this figure has been removed, the Applicants respectfully submit that the pending objections are moot.

The Applicants now turn to Figure 32. This figure was objected to as it allegedly has different views that need to be numbered separately. Figure 32 has been renumbered Figure 31. Furthermore, this figure has been separated out into Figures 31A-D so that each view is numbered separately. Certain views previously contained in the figure have been deleted. No new matter has been added by this amendment. Applicants respectfully request entry of this amendment. As the Replacement Drawings number each view separately, the Applicants respectfully submit that the objection has been overcome.

The Applicants now turn to Figure 33. This figure was objected to as it allegedly has different views that need to be numbered separately. Figure 33 has been renumbered Figure 32. This figure also has been separated out into Figures 32A and 32B so that each view is numbered separately. No new matter has been added by this amendment. Applicants respectfully request entry of this amendment. As the Replacement Drawings number each view separately, the Applicants respectfully submit that the objection has been overcome.

The Applicants now turn to Figures 34A and 34B. Figures 34A and 34B were objected to for allegedly showing different views that need to be numbered separately. Figure 34A has been deleted. Figure 34B has been renumbered Figures 33A-C so that each view is numbered separately. Reference numbers 3403 and 3405 have been added. Support for this amendment can be found at page 25, lines 21-28 of the instant Application. No new matter has been added by this amendment. Applicants respectfully request entry of this amendment. As the Replacement Drawings number each view separately, the Applicants respectfully submit that the objection has been overcome.

II. STATUS OF THE SPECIFICATION

The Applicants have amended pages 5, 18, 21, 24, 25 and 26 of the specification to properly reflect the numbering changes made in the Figures. No new matter has been added in these amendments to the specification. Applicants respectfully request entry of these amendments.

III. STATUS OF THE CLAIMS

Claims 11-13, 30-33, 35, 39, 56, 60, 61, 64, 67-69, 71, 72 and 74-80 are currently pending. Claims 11-13, 30-33, 35, 39, 56, 60, 61, 64, 67-69, 71, 72 and 74-80 currently stand rejected. By this Amendment, claims 30, 33, 56, 61, 64, 67, 68 and 74 have been amended. Applicants respectfully request entry of these amendments.

The Applicants now turn to Claim 30. Claim 30 was objected to because of the alleged informality caused by using the phrase "implant comprising" twice. As currently amended, claim 30 now recites "[a]n assembled graft implant comprising two or more individual segments fastened together with at least one pin machined from cortical bone, wherein at least one segment is a demineralized segment of allograft bone and at least one segment is a mineralized segment of allograft cortical bone, each segment having a hole drilled therein for receiving and frictionally engaging said at least one pin." No new matter has been added by this amendment. Support for this amendment can be found, for example, at page 15, lines 8-20 of the instant Application. Applicants respectfully submit that the objection has been overcome and respectfully request entry of this amendment.

The Applicants now turn to Claim 33. As currently amended claim 33 now recites "a[n] assembled graft implant suitable for use in humans comprising two or more segments of allograft cortical bone fastened together, said implant further comprising at least one pin holding said segments together." No new matter has been added by this amendment. Support for this amendment can be found, for example, at page 15 lines 8-20 of the instant Application. Applicants respectfully request entry of this amendment.

The Applicants now turn to Claim 56. Claim 56 was rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention. Specifically, claim 56 was rejected as it allegedly appears to claim an implant in both the assembled and unassembled state. As

currently amended, claim 56 now includes the following claim language: "at least one pin machined from cortical bone said at least one pin capable of interconnecting said assembleable parts and capable of holding them in juxtaposition to one another." The specification clearly discloses the inclusion of a pin that is capable of interconnecting assembleable parts and holding them in juxtaposition to one another. See, e.g., Specification at page 6, lines 20-22, page 7, lines 25-27, and page 9, lines 11-15. Thus, no new matter has been added by this amendment. Applicants submit that this rejection has been overcome and respectfully request entry of this amendment.

The Applicants now turn to Claim 61. Claim 61 was objected to because it was allegedly confusing to use the word "comprising" in line 3 of the claim. The Applicants have deleted the word "comprising" from the third line of claim 61. Applicants believe that this amendment is grammatical in nature and does not change the scope of the claim. Additionally, Applicants have added the phrase "with at least one pin." Support for this can be found, for example, at page 15, lines 8-80 of the instant Application. No new matter has been added. The Applicants submit that the current objection to claim 61 has been overcome and respectfully request entry of this amendment.

The Applicants now turn to claims 61, 64, 67 and 68. Claims 61, 64, 67 and 68 have been amended to include the phrase "with at least one pin" (claim 61) and "at least one pin" (claims 64, 67 and 68). Support for this amendment can be found, for example, at page 15, lines 8-20 of the instant Application. No new matter has been added. Applicants respectfully request entry of this amendment.

The Applicants now turn to the objection of Claim 74. Claim 74 was objected to because the language "an assembled implant comprising different segments" was allegedly confusing. Claim 74 was also objected to because allegedly the use of the word "or" more than once in an alternative statement was allegedly confusing. Claim 74 has been amended to recite "[t]he assembled implant of claim 67, wherein the implant comprises different segments of cortical bone, cancellous bone, demineralized cortical bone, demineralized cancellous bone, synthetic material, or combinations thereof." Applicants believe that this amendment is grammatical in nature and does not change the scope of the claim. No new matter has been added by this amendment. Applicants submit that the current objections to claim 74 have been overcome and respectfully request entry of this amendment.

Claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71, 72 and 74-80 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Siebels et al. (EP 0517030) in view of Coates et al. (U.S. Patent No. 5,989,289). Applicants respectfully traverse this rejection for the reasons stated in Section IV below.

IV. Rejection of Claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71, 72 and 74-80 Under 35 U.S.C. § 103(a)

Claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71, 72 and 74-80 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Siebels reference (European Patent Application No. 0517030) in view of the Coates reference (U.S. Pat. No. 5,989,289). The Applicants respectfully traverse this rejection because a *prima facie* case of obviousness has not been made. In order for a prima facie case of obviousness to be established, the Manual of Patent Examining Procedure (MPEP) states:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the teaching. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art.

MPEP §2142 (emphasis added). "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness." See id. Applicants respectfully submit that no prima facie case of obviousness has been established because: (1) there is no basis within the cited art from which it would have been obvious to one of ordinary skill in the art to combine Siebels and Coates; (2) there would have been no reasonable expectation of success in combining Siebels and Coates; and (3) not all the claim limitations of the rejected claims are taught by Siebels and Coates.

A. The Cited References, Combined As A Whole, Do Not Provide A Basis For Combining The Siebels Reference With the Coates References To Arrive At The Subject Matter Of Claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71, 72 and 74-80

When the substance and teachings of the Siebels references and the Coates reference are

properly considered, there is no basis within the cited art upon which one of ordinary skill in the art would have combined the teachings of Siebels and Coates to arrive at the subject matter of any of claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71, 72 and 74-80. Appellants respectfully submit that the Siebels reference and the Coates reference would not be combined by one of ordinary skill, particularly when each of the references is considered in its entirety.

The final Office Action admits that "Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6)." October 31, 2006 Office Action at p. 5. The Applicants respectfully believe that the pending rejection under 35 U.S.C. § 103(a) discounts the teachings of Siebels with respect to manufacturing and the reasons for which Siebels utilizes the materials disclosed therein.

> The Siebels reference describes the basis of the invention in the following manner:
>
> Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which – from the standpoint of manufacturing engineering – can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

Siebels, English Translation, p. 2. Ease of manufacturing and rapidity of implantation are thus aspects of the basis for the Siebels invention, and serve as the solutions for the nature of the problem addressed by Siebels. To achieve the aspect of "ease" of manufacturing, Siebels relies upon cutting disks out of a "prefabricated solid or hollow strand." Id. at p. 3.

The only materials actually described in the Siebels reference for making the disks and/or anchoring pins are "fiber reinforced plastic" and "carbon-fiber reinforced plastic." Specifically, on page 3, the Siebels reference states, "The disk-shaped implant is preferably made of fiber-reinforced plastic," and on page 6, the Siebels reference states that "the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means – according to the design of the implant – can consist of the same, or another material." Id. at pp. 3, 6. The Siebels reference, however, does not describe any other materials from which its implants or anchoring pins can be made.

With respect to the anchoring pins disclosed in the Siebels reference, there is no discussion, aside from the one reference to carbon-fiber reinforced plastic on page 6, of suitable materials from which they can be made. Nor is there any discussion of the parameters or factors that should be considered when choosing the material from which to make the anchoring pins.

There is thus no teaching within the Siebels reference to guide one of ordinary skill in the art in choosing any material for the anchoring pins other than carbon-fiber reinforced plastic.

With respect to the disks used for the implants described in the Siebels reference, the Siebels reference contains the following discussion:

> From the standpoint of manufacturing engineering, annular disks or solid disks can easily be manufactured of any biologically compatible material because they are not bound to a particular shaping. The shape can even partially be matched to the manufacturing method. Manufacturing methods, which are adequate for the series-manufacturing are winding or pulling of bonded-fiber tubes, out of which the disks are sawn off, cut off, or separated, either as individual element or as elements for the disk packings [packages], described above.

Id. at 10. This paragraph, as well as the specification when read as a whole, shows that the general statement regarding "any biologically compatible material" is actually limited in scope and does not extend to disks made from cortical bone such as those described and claimed in the present application. The manufacturing methods by which the implants of Siebels can "easily be manufactured" in accordance with the "basis of the [proposed] invention" make it evident that the only suitable materials are the plastics described therein. Id. at p. 2. The easy manufacturing techniques of Siebels are further described in the following manner:

> Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.
>
> Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.

Id. at pp. 6–7. For example, the Siebels reference describes one embodiment by explaining that:

> The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a

> single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having a rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.

Id. at pp. 3–4. Additionally, Figures 5 and 6 of the Siebels reference provide illustrations of the manufacturing of the winding methods described in Siebels and the disks cut therefrom. The implants of Siebels are thus characterized by the ease with which they can be manufactured. The structure and shape of the disks described by Siebels are dictated by the braided or wound stands from which they are cut, and even the strength and rigidity of the disks is a result of the oriented fibers that result from the manufacturing techniques. The manufacturing methods taught in the Siebels reference that achieve the described advantages may be suitable for use with the plastics described in Siebels, but they could not be performed on cortical bone. There is no basis within Siebels from which one of ordinary skill in the art would conclude that the manufacturing techniques could be altered or disregarded in making the disks taught therein.

The Applicants respectfully submit that under pursuant to MPEP § 2145(X)(D)(1), the teachings of the Siebels reference have not been properly considered. The MPEP explains that "[a] prior art reference that 'teaches away' from the claimed invention is a significant factor to be considered in determining obviousness." MPEP §2145(X)(D)(1). Further, "[a] prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant." Monarch Knitting v. Sulzer, 139 F.3d 877, 885 (Fed. Cir. 1998). In reading the Siebels reference, one of ordinary skill would be led towards the ease of manufacturing obtained by using the plastics and manufacturing methods described in Siebels and would therefore be led in a divergent direction from developing different manufacturing techniques to allow the use of bone as a manufacturing material. Thus, the Applicants respectfully believe that when the teachings of the Siebels reference are considered as a whole, a rejection of claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71, 72 and 74-80 under 35 U.S.C. § 103(a) is improper.

Additionally, the Coates reference, when considered as a whole, does not provide a

reason to use the cortical bone in the implants of Siebels.

As an initial matter, the implants disclosed in the Coates reference differ from the implants and portions of implants claimed in the present application in several respects. As described in Coates, "[t]he spacer 110 includes an anterior wall 111 having opposite ends 112, 113, a posterior wall 115 having opposite ends 116, 117 and two lateral walls 120, 121. Each of the lateral walls 120, 121 is connected between the opposite ends 112, 113, 116, 117 of the anterior 111 and posterior 115 walls to define a chamber 130. The walls are each composed of a bone composition, preferably cortical bone." Coates, Col. 5, ln. 66 to Col. 6, ln. 5. In contrast to the claimed implants of the present application, the Coates reference does not describe spacers made from multiple pieces of cortical bone, nor does it describe connecting pieces using cortical bone pins.

The problem addressed by the Coates reference is the issue of developing implants made of bone that "avoid the disadvantages of metal implants." Id. at Col. 4, lns. 8–16. In describing the benefits of the implants described therein, the Coates reference states:

> One benefit of the spacers of the present invention is that they combine the advantages of bone grafts with the advantages of metals, without the corresponding disadvantages. An additional benefit is that the invention provides a stable scaffold for bone ingrowth before fusion occurs. Still another benefit of this invention is that it allows the use of bone grafts without the need for metal cages or internal fixation, due to the compressive strength of the spacer and the means for resisting migration.
> Id. at Col. 4, lns. 8-16.

Notably, the Coates reference does not discuss plastic implants, or the advantages or disadvantages thereof as compared to either metal or bone implants. The Coates reference does not provide any teaching with respect to the possibility or desirability of substituting the use of bone in other grafts, such as those of the Siebels reference, that are made from plastic.

With respect to materials and manufacturing methods, the Coates reference provides the following description:

> The spacers of this invention are preferably formed of a bone composition or material. The bone may be autograft, allograft, xenograft or any of the above prepared in a variety of ways. Cortical bone is preferred for its compressive strength. In one embodiment, the spacers are obtained as a cross sectional slice of a shaft of a long bone. For example, various shaped spacers may be obtained by machining a cortical ring into the desired configuration. The exterior surfaces of the walls can be formed by machining the ring to a D-shape. Material from the

> medullary canal of the ring can be removed to form a chamber. Surface features and migration resistance means can be defined into the surface of the spacers using conventional machining methods and a standard milling machine which have been adapted to bone. Various methods and procedures are known for treating and processing bone to provide bone materials and compositions. These methods and procedures can be applied to the present invention as long as the resulting bone material provides a sufficient compressive strength for the intended application.

Id. at Col. 11, lns. 42-60. Thus, the known methods of manufacturing described in Coates require modifications in order to adapt the equipment for use with bone. Further, in the Background section provided therein, the Coates reference discusses some of the disadvantages and difficulties that were known with respect to making implants from bone:

> Both allograft and autograft present additional difficulties. Graft alone may not provide the stability required to withstand spinal loads. Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery as well as the disadvantages of metal fixation devices. Also, the surgeon is often required to repeatedly trim the graft material to obtain the correct size to fill and stabilize the disc space. This trial and error approach increases the length of time required for surgery. Furthermore, the graft material usually has a smooth surface which does not provide a good friction fit between the adjacent vertebrae. Migration and expulsion of the graft may cause neural and vascular injury, as well as collapse of the disc space. Even where such slippage does not occur, micromotion at the graft/fusion-site interface may disrupt the healing process that is required for fusion.
>
> Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible.

Id. at Col. 3, lns. 17-40. By this statement, Coates teaches that cortical bone was not a traditional orthopedic implant material for spinal implants. Rather, it was considered "extremely difficult or impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. And, although the Coates reference goes on to describe its single piece bone implants as providing one solution to the difficulties associated with using bone implants, the Coates reference when read as a whole does not provide a teaching that bone can simply be substituted as a manufacturing material in any type of implant.

The Applicants respectfully submit that the final Office Action improperly discounts the

teachings of the Coates reference in making the pending obviousness rejection. Instead of considering the teachings of the Coates reference, the final Office Action contends that Coates "teaches that it was known to make similar spinal implants [to those of Siebels] out of allograft or autograft cortical bone because of its superior properties in vivo." However, the Coates implants are single piece implants, not multiple piece implants such as those disclosed in the Siebels reference. Further, Coates does not address or overcome the advantages associated with fiber reinforced plastic, so as to motivate one skilled in the art to disregard the advantages associated with the ease of construction and stated advantages of the Siebels teachings.

In light of the disclosures of the Siebels reference and the Coates reference when read in their entirety, there simply would have been no reason to combine the Siebels reference and the Coates reference to arrive the subject matter of any of claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71, 72 or 74-80. "A critical step in analyzing the patentability of claims pursuant to Section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000). When this critical step is taken with respect to the Siebels reference and the Coates reference, it becomes apparent that given the "extremely difficult or impossible" setting of developing an implant from cortical bone as described in the Coates reference, one skilled in the art would not have had a reason to substitute cortical bone of Coates for the "extraordinarily easy" to use braided or wound plastics of Siebels. Moreover, given the art recognized extreme difficulty or impossibility of developing a single piece implant from cortical bone as disclosed in Coates, one skilled in the art would not have modified the teachings of Coates to build an implant assembled from multiple segments of cortical bone held together with bone pins.

Applicants respectfully submit that the pending rejection under 35 U.S.C. §103(a) is improper because it is based on the picking and choosing of isolated elements from the cited references, and then combining these elements in the absence of a reason provided within the art to do so. It is not permissible to pick and choose among the individual elements of assorted prior art references to re-create the claimed invention. Accordingly, the Applicants respectfully request that the obviousness rejection over the Siebels reference in view of the Coates reference be withdrawn.

B. No Basis For A Reasonable Expectation Of Success Has Been Established With Respect To Combining The Siebels Reference And The Coates Reference To Arrive At The Subject Matter Of Claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71, 72 and 74-80

The MPEP also requires that "there must be a reasonable expectation of success" that must be found in the prior art. MPEP § 2142. With respect to the present application, there has been no articulation of any basis for a reasonable expectation of success in the prior art related to using cortical bone to manufacture implants and portions of implants made from multiple pieces held in juxtaposition by cortical bone pins, as described and claimed by the Applicants. In light of this, the Applicants respectfully believe that the rejection under 35 U.S.C. § 103(a) is improper and should be withdrawn.

When addressing the issue of a reasonable expectation of success, the MPEP explains, "[o]bviousness does not require absolute predictability, however, at least some degree of predictability is required." MPEP § 2143.02. The MPEP further states, "[w]hether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made." MPEP § 2143.02. When the cited prior art references are viewed in this context, it becomes apparent that they do not provide a reasonable expectation of success with respect to substituting cortical bone as a manufacturing material into the implant pieces of the Siebels reference. For example, given the difficulties with making bone grafts as described in the Coates reference, there would not have been a reasonable expectation of success that implants could be assembled from multiple pieces of cortical bone.

Further, both the Coates reference and the Siebels reference discuss the need for implant strength, but neither addresses whether cortical bone pieces held in juxtaposition would provide such strength. For example, the Coates reference expresses the concern that "[g]raft alone may not provide the stability required to withstand spinal loads," and then states that "the spacers of this invention stimulate bone ingrowth like a bone graft and provide sufficient strength to support the vertebral column but avoid the disadvantages of both bone graft and metal implants...." Coates, at Col. 3, lns. 18-19; Col. 5, lns. 21-24. Similarly, the Siebels reference describes that the fiber reinforced plastic implants disclosed therein "are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant." Siebels, at p. 3. Thus, while the Coates and Siebels

references each describe that their own implants provide the necessary strength, neither one provides a basis from which it could be concluded that cortical bone pieces held in juxtaposition by cortical bone pins would successfully provide this property.

Because the combination of references in the pending obviousness rejection is not based upon any reasonable expectation of success found in the prior art, the Applicants believe that a *prima facie* case of obviousness has not been made. The Applicants, therefore, respectfully requires that the rejection be withdrawn.

C. Siebels In View of Coates Does Not Disclose All The Claim Limitations

In order for a claim to be rejected under § 103(a), the reference or combined references must teach or suggest all the claim limitations. The combination of Siebels and Coates does not teach or suggest all the claim limitations of at least claims 11, 12, 30, 39, 60, 61 and 80.

The Applicants now turn to the rejection of claim 30. Claim 30 of the instant application claims "[a]n assembled graft implant comprising two or more individual segments fastened together with at least one pin machined from cortical bone, wherein at least one segment is a demineralized segment of allograft bone and at least one segment is a mineralized segment of allograft cortical bone . . ." The October 31, 2006 Office Action states that "the spacers of Coates have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Any segment thereof would be a demineralized segment or a mineralized segment." The Applicants respectfully disagree. Claim 30 recites at least two segments of bone held together by at least one pin of cortical bone. Claim 30 further requires that at least one segment is a mineralized segment, and at least one segment is a demineralized segment. The Office Action, however, fails to identify each of the elements of at least one pin, at least one demineralized bone segment, and at least one mineralized bone segment. The Office Action seems to contemplate that the Siebels' pin forms its own segment. As stated above, however, Claim 30 recites at least two segments of bone and at least one pin of cortical bone.

Furthermore, neither reference discusses creating segments of bones, at least one of which is mineralized and at least one of which is demineralized. Rather, Coates teaches the use of a spacer and Siebels teaches the use of plastic to make an implant. The implants taught by

Siebels and Coates, therefore, do not teach an implant with at least one mineralized segment and at least one demineralized segment. Therefore, Applicants submit that the current rejection of Claim 30 should be withdrawn. Because claims 31, 32 and 35 depend from claim 30, the Applicants respectfully believe that the current rejection of claims 31, 32 and 35 should also be withdrawn.

Claim 80 is directed to a bone implant "wherein at least one of said two or more bone segments is a mixed composition segment." The specification of the instant Application defines as a "mixed composition segment" as:

> an allograft implant that is comprised of two or more regions having different characteristics and/or properties. For example, a mixed composition segment can comprise a region comprising demineralized bone or mineralized bone attached to another region comprising a synthetic material.... Also, when referring to a particular mixed-composition segment, the segment may be described as a "demineralized segment comprising a region of mineralized bone," and this is taken to mean a segment that has at least one region of mineralized bone and at least one region of demineralized bone.

Specification at page 10, lines 20–30. Neither Coates nor Siebels disclose creating bone segments that have regions with different properties – i.e. mineralized and demineralized regions in the same segment. Therefore, the Applicants respectfully believe that the current rejection of Claim 80 should be withdrawn.

The Applicants now turn to the rejection of claim 60. Claim 60 is directed to "[a]n assembled implantable bone graft suitable for implantation in humans comprising segments of allograft cortical bone held in juxtaposition by machined pins of cortical bone wherein, prior to assembly the bone pins are pre-shrunk by freeze drying." The October 31, 2006 Office Action, relying on MPEP § 2113, stated that "[t]he [pre-shrunk pins] method step does not clearly result in a different product as that suggested by Siebels as modified by Coates." Applicants respectfully disagree. MPEP § 2113 provides that "[t]he structure implied by the process step should be considered when assessing the patentability of product-by-process claims over the prior art, especially when . . . the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." MPEP § 2113. The specification of the instant application provides that freeze drying in this manner allows the pins and the segments to "be assembled together such that the requisite friction is achieved to keep the parts securely together." Specification at page 14, lines 10-14. This step solves the problem of having

pins and holes that are not of the same size. See Specification at page 13, lines 16-25. Thus, the structure of the invention claimed in claim 60 is different from the prior art in that the pins and holes of the claim 60 fit together with the requisite friction needed to keep the parts securely together. Accordingly, the Applicants respectfully request the Examiner's rejection of claim 60 to be withdrawn.

The Applicants now turn to the rejection of claim 61. Claim 61 is directed to "[a]n assembled implantable bone graft suitable for use in humans comprising a first machined segment of allograft bone pinned to a second machined segment of allograft bone, and a flexible tissue affixed between said first segment and said second segment." The October 31, 2006 Office Action stated that "since bone is inherently flexible to some extent, the middle disk of Siebels as modified by Coates would meet the claim language calling for flexible tissue." As discussed throughout the specification of the instant application, flexibility can be important depending the purpose and location of the implant. Normally flexibility is not considered a property of untreated bone. For example, the specification of the instant application provides that:

> [t]hose skilled in the art will appreciate from this disclosure that segment **F**, segment **D**, or segment **E** [of Figure 3] may be demineralized according to methods known in the art. Likewise, all of these segments may be demineralized. Where flexibility is important in one dimension and structural support is also required, one solution is to have one or more segments of an [sic] composite bone graft be a mixed-composition segment which comprises at least one mineralized region and at least one demineralized region . . ..

Specification at page 15, lines 13-20. The specification of the instant application further provides that:

> the degree of demineralization spans a broad range, with increased exposure to acid (whether by time, acidity or solution, frequency of change-out of solution, or any combination) resulting in a more demineralized, more flexible material. Thus, an implant or implant region may be partially demineralized, wherein some minerals remain and there is a range of flexibility. Alternatively, an implant or implant region may be fully demineralized, wherein the minerals are basically removed and there is a maximum flexibility. . . .
>
> * * *
>
> An allograft segment as described above can be combined with other allograft segments as exemplified in Figure 29. Figure 29 shows a first segment **2901**, that

> is fully mineralized, and a second segment, **2903**, that is also fully mineralized. Positioned between these segments is a mixed allograft segment, **2902**, such as described above in Figure 28. . . . Once assembled, this allograft assembly can be used in a patient in need of a degree of flexibility in the A-A dimension. Such flexibility is provided largely by the flexibility of the partially or fully demineralized side regions of the mixed composition allograft segment, **2902**. Additional flexibility may be provided by the flexibility of the pins, **2904**, and the spacing between the segment, **2905**.

Specification at page 20, line 29 – page 21 line 27.

Furthermore, neither Coates nor Siebels teach or suggest that flexibility is desired in any part of bone implants. For example, Siebels is directed towards an implant with a "rigid element." Siebels at pages 1 and 14. Moreover, Siebels teaches the use of an implant that has "disks [that] are radially connected to one another, and also in such a way [i.e. possess torsional strength], and cannot rotate." Siebels at page 5. Even further, Siebels teaches the use of a "hardening material" and/or filling up the hollow space with "extraneous bone material, or with the patient's own bone material, or with bone cement." Siebels at page 5 and 11. Therefore, nothing in Siebels teaches an assembled implant bone graft comprising a flexible tissue. Similarly, Coates is directed towards an implant that that has "the biomechanical properties of metal" so that the implant provides "sufficient strength to support the vertebral column." Coates at col. 3, lns. 35-42. Thus, both Siebels and Coates teach that rigidity is important. They teach nothing regarding an assembled implant bone graft comprising a flexible tissue. Therefore, Applicants respectfully submit that "the middle disk of Siebels as modified by Coates" would not meet the claim language calling for a flexible tissue. Accordingly, the Applicants respectfully request that the instant rejection of claim 61 be withdrawn.

Finally, the Applicants turn to claims 11, 12 and 39. Claims 11, 12 and 39 involve implants that have undergone a cleaning process. These claims were rejected as unpatentable over Siebels in view of Coates. In particular, the Examiner, citing MPEP § 2113 stated that "any difference resulting from the process steps would at most result in only a slight difference between the claimed invention and the invention disclosed by Siebels." The Applicants respectfully disagree. The specification provides in part that:

> In developing the various embodiments of the present invention, one technical issue of merit is the need to develop a process whereby donor tissue . . . may be treated in such a fashion as to eliminate the possibility of cross-contamination between tissue segments obtained from different sources. While it is possible to

> practice the present invention to advantage using tissue obtained from a single screened donor, the real economies of scale and commercial viable application of the present technology is best realized by implementation of an efficient and reliable tissue decontamination process.

Specification at page 11, lines 8-15. Accordingly, the cleaning steps of claims 11, 12 and 39 do produce a product that is different than Siebels. As such, the Applicants respectfully request that this rejection of claims 11, 12 and 39 be withdrawn.

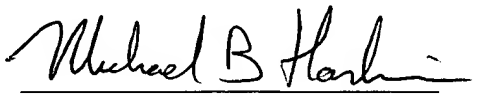
CONCLUSION

In view of the amendments and arguments provided herein, Applicants believe that the pending rejections under 35 U.S.C. § 112 and 35 U.S.C. § 103(a) have been overcome. Applicants respectfully submit that claims 11-13, 30-33, 35, 39, 56, 60, 61, 64, 67-69, 71, 72 and 74-80 are therefore in a condition for allowance.

Applicants believe that no fee is due in conjunction with the filing of this Amendment and Response. The Commissioner is, however, hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Date: March 30, 2007

Respectfully submitted,



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